



8-2-09 1615 \$
JF/K

Docket No. 57273 (47126)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: G. Cevc Confirmation No.: 9461
U.S.S.N.: 09/555,986 Group No.: 1615
FILED: August 17, 2000 Examiner: G.S. Kishore
FOR: METHOD FOR DEVELOPING, TESTING AND USING ASSOCIATES
OF MACROMOLECULES AND COMPLEX AGGREGATES FOR
IMPROVED PAYLOAD AND CONTROLLABLE DE/ASSOCIATION
RATES
08/04/2004 NROCHA1 00000008 09555986

Mail Stop: Amendment
Commissioner for Patents
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CERTIFICATE OF EXPRESS MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as Express Mail, Label No. EV 437 825 112 US addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: July 30, 2004

By:

Judy Daley

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §§1.56 and 1.97, Applicants herewith submit the publications and/or patents shown on the attached form PTO-1449, for consideration by the Examiner in connection with the examination of the above-identified patent application.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

- _____
(1) within three (3) months of the Filing Date or **before the mailing date of the First Office Action** on the merits; or

- (2) within three months of the mailing date of the Search Report issued by the PCT Patent Office; or
- (3) after the period defined in (1) but before the mailing date of a **Final Rejection or Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or
- (4) after the mailing date of a **Final Rejection or Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

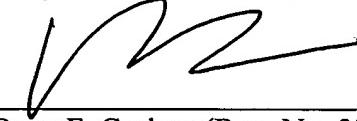
It is respectfully requested that each of the documents shown on the attached form(s) PTO-1449 be made of record in this application. Copies of these documents (CHECK ONE):

- are enclosed herewith; or
- have been cited in the parent application, and are thus not being resubmitted herein.

FEE AUTHORIZATION

Enclosed herewith is a check in the amount of \$180.00 for submission of these cited references. Should any additional fees associated with the submission be required, the Commissioner is authorized to charge the missing fee to our Deposit Account, No. 04-1105. Any overpayments should be credited to said Deposit Account.

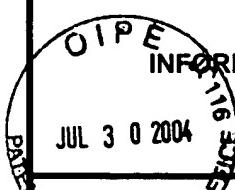
Respectfully submitted,



Peter F. Corless (Reg. No. 33,860)
Edwards & Angell, LLP
P.O. Box 55874
Boston, MA 02205
(617) 439-4444

Date: July 30, 2004

Customer No.: 21874



INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

JUL 30 2004

ATTY DOCKET NO. 57273 (47126)	SERIAL NO. 09/555,986
Applicant(s): G. CEVC	
FILING August 17, 2000	GROUP 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	5,607,692	04/04/1997	Ribier et al.	424	450	
AB	5,958,379	28/09/1999	Regenold et al.	424	47	
AC	4,911,928	27/03/1990	Wallach	424	450	
AD	5,322,685	21/06/1994	Nakagawa et al.	424	78.03	
AE	5,238,613	24/08/1993	Anderson	264	22	
AF	Re. 33,273	24/07/1990	Speaker	210	639	
AG	4,619,794	28/10/1986	Hauser	264	4.1	
AH	4,954,345	04/09/1990	Müller	424	450	
AI	4,937,078	26/06/1990	Mezei et al.	424	450	
AJ	4,921,706	01/05/1990	Roberts et al.	424	450	
AK	5,741,515	21/04/1998	Ciceri et al.	424	450	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
BA	07-324029	12.12.1995	JP				
BB	0 393 707	20.04.1990	EP				
BC	1 143 656	20.04.1990	CA				

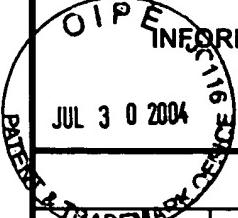
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CA	G. Cevc et al., Transdermal drug carriers: basic properties, optimization and transfer efficiency in the case of epicutaneously applied peptides, <i>J. Contr. Rel.</i> , 36, pp. 3-16, 1995
CB	S. Yuan, et al., Cationic Liposome and Gene Transfer, <i>Progress in Physiological Science</i> , 28(2), pp. 163-165, 1997

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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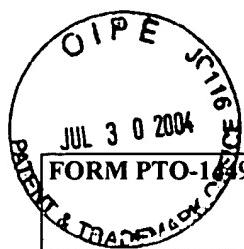
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							YES	NO
.	BD	61-271204	01.12.1986	JP				
.	BE	724218	17.10.1996	AU				
.	BF	0 152 379	11.02.85	EP				
.	BG	0 088 046	11.02.1983	EP				

OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

EXAMINER	DATE CONSIDERED
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FORM PTO-1615

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UNITED STATES PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

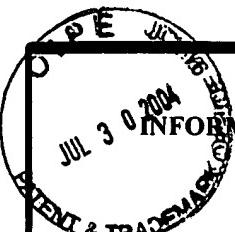
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO
	BH	WO 98/30215	16.07.1998	PCT			
	BI	WO 88/07362	06.10.1988	PCT			
	BJ	WO 98/06750	19.02.1998	PCT			
	BK	WO 91/04013	04.04.1991	PCT			
	BL	WO 92/05771	16.04.1992	PCT			
	BM	WO 93/19736	14.10.1993	PCT			
	BN	WO 93/19737	14.10.1993	PCT			

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FORM PTO-1449			DOCKET NO: 57273 (47126)	SERIAL NO.: 09/555,986		
INFORMATION DISCLOSURE STATEMENT			APPLICANT: G. CEVC			
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	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO
BO	WO 90/09782	07.09.1990	PCT			
BP	WO 87/01938	09.04.1987	PCT			
BQ	4,447,287	07.11.1996	DE			
BR	3,713,494	29.10.1987	DE			
BS	3,016,976	13.11.1980	DE			
BT	1,289,420	24.09.1991	CA			
BU	1,740,283	28.07.1983	AU			
BV	0,674,913	04.10.1995	EP			
BW	0,704,206	03.04.1996	EP			
BX	0,475,160	18.03.1992	EP			
BY	0,707,847	24.04.1996	EP			
BZ	0,280,492	31.08.1988	EP			
BAA	0,102,324	07.03.1984	EP			
BBB	0,224,837	24.11.1986	EP			
BCC	0,211,647	25.02.1987	EP			
BDD	0,220,797	06.05.1987	EP			
EXAMINER:				DATE:		


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(Use several sheets if necessary)

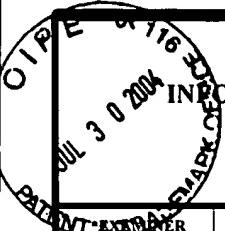
Docket Number (Optional) 57273 (47126)	Application Number 09/555,986
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Filing Date August 17, 2000	Group Art Unit 1615

*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>	
CC	G. Cevc, Transfersomes, Liposomes and Other Lipid Suspensions on the Skin: Permeation Enhancement, Vesicle Penetration, and Transdermal Drug Delivery, <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 13(3&4), pp. 257-388, 1996	
CD	T. Henmi, et al., "Application of an Oily Gel Formed by Hydrogenated Soybean Phospholipids as a Percutaneous Absorption-Type Ointment Base," <i>Chem. Pharm. Bull.</i> , 42(3), pp. 651-655, 1994	
CE	Benner, "The Human Body, The Wonderwork of the Human Body, Structure, Functions, Interactions, Processes and Mechanisms," <i>Weltbild GmbH Augsburg</i> (1995)	
CF	Serva, FEINBIOCHEMICA FUR FORSCHUNG for <i>Serva Feinbiochemica GmbH & Co.</i> (1986/1987)	
CG	Clark, J.M., Jr., "Experimental Biochemistry" Biochemistry Division, Department of Chemistry, University of Illinois, pp. 47-48	
CH	Patel, H.M., "Liposomes as a Controlled-release System" Biomedical Society Transactions 609th Meeting, Leeds, pp 513-516	
CI	Fieser, L.F., et al. "Organische Chemie" <i>Hans Ruprecht Hensel, 2nd revised edition, Verlag Chemie GmbH, Weinheim/Bergstr</i> (1968)	
CJ	Fluka Chemika-BioChemika Catalogue 16 (1988/89)	
CK	Roeding, J., "Liposomes and Niosomes in Pharmacy and Cosmetic State of the Art Prospects, Techniques of Visualizing Vesicular Systems, Interaction of Liposomes with the Skin" <i>Training Course No. 105 from May 14 to 16, 1990, MARITIM Hotel Nurnberg, Frauendorfgraben 11, 8500 Nurenwberg</i>	
CL	L. Löbbecke, et al., "Effects of Short-Chain Alcohols On the Phase Behavior And Interdigitation Of Phosphatidylcholine Bilayer Membranes," <i>Biochimica et Biophysica Acta</i> , 1237, pp. 59-69, 1995	
CM	R. Singh, et al., "Liposomally Encapsulated Diclofenac For Sonophoresis Induced Systemic Delivery," <i>J. Microencapsulation</i> , Vol. 12, No. 2, pp. 149-154, 1995	

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		Applicant(s) G. CEVC	
EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		
CN	M. Foldvari, et al., "Dermal Drug Delivery by Liposome Encapsulation: Clinical and Electron Microscopic Studies," <i>J. Microencapsulation</i> , Vol. 7, No. 4, pp. 479-489, 1990		
CO	M. Foldari, "In Vitro cutaneous and Percutaneous Delivery and in Vivo Efficacy of Tetracaine from Liposomal and Conventional Vehicles," <i>Pharmaceutical Research</i> , Vol. 11, No. 11, 1994		
CP	M. Foldari, "Effect of Vehicle on Topical Liposomal Drug Delivery: Petrolatum Bases," <i>J. Microencapsulation</i> , Vol. 13, No 5, pp. 589-600, 1996		
CQ	M.E. Planas, et al., "Noninvasive Percutaneous Induction of Topical Analgesia by a New Type of Drug Carrier, and Prolongation of Local Pain Insensitivity by Anesthetic Liposomes," <i>Anesth. Analg.</i> , 75, pp. 615-621, 1992		
CR	H. Peters, et al., "Pharmacodynamics of a Liposomal Preparation for Local Anaesthesia," <i>Arzneim.-Forsch./Drug Res.</i> , 45(II), Nr. 12, 1995		
CS	I. Stoye, et al, "Transformation of a Liposomal Dispersion Containing Ibuprofen Lysinate and Phospholipids into Mixed Micelles - Physico-chemical Characterization and Influence on Drug Permeation through Excised Human StratumCorneum," <i>European Journal of Pharmaceutics and Biopharmaceutics</i> , 46, pp. 191-200, 1998		
CT	J. Schramlova, et al., "The Effect of an Antiphlogistic Incorporated in Liposomes on Experimentally Induced Inflammation," <i>Folia Biologica (Praha)</i> , 43, pp. 195-199, 1997		
CU	G. Cevc, "Drug Delivery Across the Skin," <i>Exp. Opin. Invest. Drugs</i> , 6(12), pp. 1887-1937, 1997		
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OTHER DOCUMENTS							
CV	G. CEVC et al., Transfersomes-mediated transepidermal delivery improves the regio-specificity and biological activity of corticosteroids <i>in vivo</i> , <i>Journal of Controlled Release</i> 45 (1997) 211-226						
CW	V.M. KNEPP et al., CONTROLLED DRUG RELEASE FROM A NOVEL LIPOSOMAL DELIVERY SYSTEM II. TRANSDERMAL DELIVERY CHARACTERISTICS," <i>Journal of Controlled Release</i> , 12 (1990) March, No. 1, Amsterdam, NL, pp. 25-30						
CX	C.E. Price, "A REVIEW OF THE FACTORS INFLUENCING THE PENETRATION OF PESTICIDES THROUGH PLANT LEAVES" on I.C.I. Ltd., Plant Protection Division, Jealott's Hill Research Station, Bracknell, Berkshire RG12 6EY, U.K., pp. 237-252						
CY	K. Karzel and R. K. Liedtke, "MECHANISMEN TRANSKUTANER RESORPTION" on Grandlagen/Basics, pp. 1487-1491						
CZ	Michael Mezei, "LIPOSOMES AS A SKIN DRUG DELIVERY SYSTEM" 1985 Elsevier Science Publishers B.V. (Biomedical Division), pp. 345-358						
CAA	Adrienn Gesztes and Michael Mezei, "TOPICAL ANESTHESIA OF THE SKIN BY LIPOSOME-ENCAPSULATED TETRACAINE" on <i>Anesth Analg</i> 1988; 67: pp. 1079-81						
CBB	A. Helenius, et al, "SOLUBILIZATION OF MEMBRANES BY DETERGENTS," <i>Biochimica et Biophysica Acta</i> , 415 (1975) 29-79						
CCC	Phillip G. Green, et al., "IN VITRO AND IN VIVO ENHANCEMENT OF SKIN PERMEATION WITH OLEIC AND LAURIC ACIDS" on <i>International Journal of Pharmaceutics</i> , 48 (1988), pp. 103-111						
CDD	Guia M. Golden et al., "ROLE OF STRATUM CORNEUM LIPID FLUIDITY IN TRANSDERMAL DRUG FLUX" on <i>Journal of Pharmaceutical Sciences</i> , Vol. 76, No. 1, January 1987, American Pharmaceutical Association, pp. 25-28						
CEE	Bruce J. Aungst et al., "ENHANCEMENT OF NALOXONE PENETRATION THROUGH HUMAN SKIN IN VITRO USING FATTY ACIDS, FATTY ALCOHOLS, SURFACTANTS, SULFOXIDES AND AMIDES" on <i>International Journal of Pharmaceutics</i> , 33 (1986) pp. 225-234						



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OTHER DOCUMENTS							
	CFF	Ronald R. Burnette et al., "CHARACTERIZATION OF THE PERMSELECTIVE PROPERTIES OF EXCISED HUMAN SKIN DURING LONTOPHORESIS" on <i>Journal of Pharmaceutical Sciences</i> , Vol. 76, No. 10, October 1987, American Pharmaceutical Association, pp. 765-773					
	CGG	E.C. Katoulis et al., "EFFICACY OF A NEW NEEDLESS INSULIN DELIVERY SYSTEM MONITORING OF BLOOD GLUCOSE FLUCTUATIONS AND FREE INSULIN LEVELS" on <i>International Journal of Artificial Organs</i> , Vol. 12, No. 5, 1989, pp. 333-338					
	CHH	Ovals Siddiqui et al., "NONPARENTERAL ADMINISTRATION OF PEPTIDE AND PROTEIN DRUGS" on <i>CRC Critical Reviews in Therapeutic Drug Carrier Systems</i> , Volume 3, Issue 3, pp. 195-208					
	CII	Cevc, G. et al., "Ultraflexible vesicles, Transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin," <i>Biochimica et Biophysica Acta</i> . 1368 pp. 201-215 (1998)					
	CJJ	Cevc, G., "Material Transport Across Permeability Barriers by Means of Lipid Vesicles," <i>Handbook of Biological Physics</i> , Vol. 1, pp. 465-490 (1995)					
	CKK	Mayer, L.D. et al., "Vesicles of variables sizes produced by a rapid extrusion procedure," <i>Biochimica et Biophysica Acta</i> , 858 pp. 161-165 (1986)					
	CLL	Patel, H.M. et al., "ORAL ADMINISTRATION OF INSULIN BY ENCAPSULATION WITHIN LIPOSOMES," <i>FEBS LETTERS</i> , 62(1):60-63 (February 1976)					
	CMM	Schreier, H., "Liposomes – A Novel Drug Carrier, I. Phospholipids; Production and Characterization of Liposomes; II. Destiny of liposomes in vivo; use in therapy," <i>Pharmazie in unserer Zeit</i> , No. 4 (1982)					
	CNN	Beyer, C. et al., "Micro Emulsions" <i>Pharmazie in unserer Zeit</i> , No. 2 (1983)					
	COO	Lichtenberg, D. et al., "SOLUBILIZATION OF PHOSPHOLIPIDS BY DETERGENTS STRUCTURAL AND KINETIC ASPECTS" <i>Biochimica et Biophysica Acta</i> , 737 pp. 285-304 (1983)					
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CPP	Lasch, J. et al., "Interactions of external lipids (lipids vesicles) with the skin" <i>Journal of Liposome Research</i> , 5(3) pp. 543-569 (1995)						
CQQ	Berger, M., "Oral Insulin 1922-1992: The History of Continuous Ambition and Failure" Heinrich-Heine-University, Dusseldorf, Germany						
CRR	Cevc. G. et al., "The skin: a pathway for systemic treatment with patches and lipid-based agent carriers" <i>Advanced Drug Delivery Reviews</i> 18 pp. 349-378 (1996)						
CSS	M.L. Jackson, et al., "SOLUBILIZATION OF PHOSPHATIDYLCHOLINE BILAYERS BY OCTYL GLUCOSIDE," <i>biochemistry</i> , 1982, 21, 4576-4582						
CTT	P. Vinson, et al., "VESICLE-MICELLE TRANSITION OF PHOSPHATIDYLCHOLINE AND OCTYL GLUCOSIDE ELUCIDATED BY CRYO-TRANSMISSION ELE TRON MICROSCOPY," <i>Biophys. J.</i> , <i>Biophysical Society</i> , Volume 56 October 1989 669-681						
CUU	K. Edwards, et al., "EFFECTS OF TRITON X-100 ON SONICATED LECITHIN VESICLES," <i>Langmuir</i> , Vol. 5, No. 2, 1989 pp. 473-478						
CVV	A. Brendzel, et al., "EFFECTS OF LIPID-SOLUBLE SUBSTANCES ON THE THERMOTROPIC PROPERTIES OF LIPOSOME FILTRATION," <i>Biochimica et Biophysica Acta</i> , 601 (1980) 260-270						
CWW	G. Blume, et al., "DRUG-CARRIER AND STABILITY PROPERTIES OF THE LONG-LIVED LIPID VESICLES, CRYPTOSOMES, IN VITRO AND IN VIVO," <i>Journal of Liposome Research</i> , 2(3), 355-368 (1992)						
EXAMINER:				DATE:			